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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,520	03/09/2006	Sarah C. Bodary-Winter	GNE-0274 R1	6697

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Goodwin Procter LLP
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EXAMINER	
KEMMERER, ELIZABETH	
ART UNIT	PAPER NUMBER
1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,520	BODARY-WINTER ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/8/05, 9/18/06, 1/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group X, claims 18 and 20, in the reply filed on 28 October 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Application, Amendments, And/Or Claims

The preliminary amendments of 09 March 2006 and 28 October 2008 have been entered in full. Claims 1-19 and 21-26 are canceled. Claims 20 and 27-30 are under examination.

Specification

The disclosure is objected to because of the following informalities: The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods of diagnosing an immune related disease in a mammal comprising determining expression level of PRO96271.

Appropriate correction is required.

The disclosure is also objected to because it contains multiple embedded hyperlinks and/or other form of browser-executable codes. Applicant is required to

delete the embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01. See, for example, [0071], [0078].

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not appear to refer to "PRO96271."

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "the test tissue cells" in the last two lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 27-30 recite the limitation "said antibody" in each claim. There is insufficient antecedent basis for this limitation in the claim.

35 U.S.C. §§ 101 and 112, First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 27-30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility.

The claims are directed to methods of diagnosing an immune related disease in a mammal, comprising determining the expression level of the PRO96271 polypeptide of SEQ ID NO: 70 in a test sample relative to a control, wherein overexpression of the polypeptide is indicative of an inflammatory immune response in the tested mammal. The specification discloses SEQ ID NO: 70, but does not appear to disclose "PRO96271." The specification provides no information about SEQ ID NO: 70 other than its sequence. Example 1 is noted at pp. 150-151, which are extremely preliminary results regarding expression levels of nucleic acids and proteins in activated CD4+ T-cells compared to levels in resting CD4+ T-cells. However, none of Figures 946, 1520, 1574, 1622, 1816, 2433, 2986, 3220, 4120, or 5421 appear to correlate with SEQ ID NO: 70 as recited in the claims. Thus, the specification as originally filed does not appear to even assert that PRO96271 or SEQ ID NO: 70 is overexpressed in activated T-cells, let alone in a biological sample from a mammal suffering from an immune related disease.

Furthermore, it is noted that the phrase "immune-related disease" is extremely broad, and encompasses diseases characterized by an overactive immune system

(such as an autoimmune disease or graft versus host disease) and a suppressed immune system (such as HIV-AIDS or chemotherapy patients). It defies logic to assume that a single protein is elevated in all forms of immune related diseases, including those having opposite characteristics.

There is little doubt that, after complete characterization, the protein of SEQ ID NO: 70, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is

not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Furthermore, the courts have stated that patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may not be patentable. Tossing out the mere germ of an idea does not constitute an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See *Genentech v. Novo Nordick A/S* (CAFC) 42 USPQ2d 1001 (1997).

Claims 20 and 27-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al. (1997, Nephron 75:321-326).

The claim is directed to a method of diagnosing an immune related disease in a mammal, said method comprising determining the expression level of the PRO96271 polypeptide of SEQ ID NO: 70 in a test sample relative to a normal sample, wherein overexpression of the polypeptide in the test sample is indicative of an immune related disease. It is noted that the specification does not provide a limiting definition of an "immune related disease."

Hayashi et al. disclose that aquaporin 3, which is identical to the protein of SEQ ID NO: 70, is overexpressed in patients suffering from ADPKD as compared to normal tissue. See Figures 1-5, pp. 323-324. It is noted that ADPKD patients also have elevated TNF-α levels. Since TNF-α is an inflammatory cytokine, the disease is related to inflammation, and thus to the immune system.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. (1997, Nephron 75:321-326) in view of Leung et al. (US 6,254,868 B1; issued 03 July 2001).

As discussed above, Hayashi et al. disclose that aquaporin 3, which is identical to the protein of SEQ ID NO: 70, is overexpressed in patients suffering from ADPKD as compared to normal tissue. See Figures 1-5, pp. 323-324.

Hayashi et al. use a polyclonal antibody to detect the protein, and not the antibody forms recited in claims 27-30. However, these antibody forms were well known in the art at the tie of the invention. For example, Leung et al. teach that humanized, fragment, monoclonal, and labeled antibodies are useful in diagnosis. See abstract.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Hayashi et al. by using the antibody forms

taught by Leung et a. with a reasonable expectation of success, since such would have been merely combining prior art elements according to known methods to yield predictable results.

Art of Interest

Ishibashi et al., 1995, Genomics 27:352-254. Ishibashi et al. disclose the sequence of human aquaporin-3, which is identical to the instant SEQ ID NO : 70. See alignment below, wherein instant SEQ ID NO: 70 is "Qy" and aquaporin-3 of Ishibashi et al. is "Db":

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Qy          1 MGRQKELVSRCGEMLHIRYRLLRQALAECLGTLILVMFGCGSVAQVVLSRGTHGGFLTIN 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MGRQKELVSRCGEMLHIRYRLLRQALAECLGTLILVMFGCGSVAQVVLSRGTHGGFLTIN 60

Qy         61 LAFGFAVTLGILIAGQVSGAHLNPAVTFAMCFLAREPWIKLPIYTLAQTLGAFLGAGIVF 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 LAFGFAVTLGILIAGQVSGAHLNPAVTFAMCFLAREPWIKLPIYTLAQTLGAFLGAGIVF 120

Qy        121 GLYYDAIWHFADNQLFVSGPNGTAGIFATYPSGHLDMINGFFDQFIGTASLIVCVLAIVD 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 GLYYDAIWHFADNQLFVSGPNGTAGIFATYPSGHLDMINGFFDQFIGTASLIVCVLAIVD 180

Qy        181 PYNNPVPRGLEAFTVGLVVLVIGTSMGFNSGYAVNPARDFGPRLFTALAGWGSAVFTTGQ 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 PYNNPVPRGLEAFTVGLVVLVIGTSMGFNSGYAVNPARDFGPRLFTALAGWGSAVFTTGQ 240

Qy        241 HWWWVPIVSPLLGSIAGVFVYQLMIGCHLEQPPPSNEEENVKLAHVKHKEQI 292
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 HWWWVPIVSPLLGSIAGVFVYQLMIGCHLEQPPPSNEEENVKLAHVKHKEQI 292
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Li et al., 2008, Nature Medicine 14:863-868. Li et al. disclose the involvement of TNF-α in ADPKD, thus evidencing that ADPKD is an immune-related disease.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ECK/
19 June 2009

/Elizabeth C. Kemmerer/
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Primary Examiner, Art Unit 1646